ORIENTAL SYSTEM TECHNOLOGY INC.

JUL - 9 2001

K010235

Exhibit # 1

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is : _____

1. **Submitter's Identifications:**

Oriental System Technology Inc.
2F No.23, Industry E. Road IX
Science Based Industrial Park
Hsinchu, Taiwan, R.O.C.

Contact:
Mr. Herman Lee
General Manager

Date summary prepared: January, 2001.

2. **Name of the Device**

TempTeller® Infrared Ear Thermometer, model CT-30 / CT-30DX

3. **Predicate Device Information**

- TempTeller® Infrared Tympanic Thermometer, model TT-201, Oriental System Technology Inc., 510(k) Number: K984497
- Braun ThermoScan® Instant Thermometer, model IRT 3020/3520, Braun AG, 510(k) Number: K 983295

4. **Device Description:**

The OSTI TempTeller ® Infrared Ear Thermometer, model CT-30 / CT-30DX, is an electronic thermometer using an infrared sensor to detect human body temperature from the auditory canal. Its operation is based on measuring the natural thermal radiation emanating from the tympanic membrane and the adjacent tissue.

OSTI TempTeller® Infrared Ear Thermometer, model CT-30 / CT-30DX, consists mainly of five parts: an IR sensor packed together with an ambient temperature sensor, a waveguide, a heat sink made of zinc alloy, a LCD display, and the associated circuit.

The tympanic membrane is thin and flooded with blood at the core temperature. The waveguide, usually a cylindrical pipe with a highly reflective inner surface for confining the radiation, is adaptive to the outer canal without contacting the eardrum. When inserting the probe into the ear canal, the radiative fluxes transfer among the tympanum (eardrum), the IR sensor, and the inner surface of the waveguide. The ambient sensor is packed with the IR sensor to monitor the ambient temperature of the IR sensor.

To measure core temperature, an ear thermometer is inserted into a patient's outer ear canal. An actuation button is pressed to start the measurement through the radiation exchanges. The electrical signal readouts from the IR sensor and the ambient temperature sensor are fed to the circuit for amplification, digitization and calculation. The measured temperature then appears on the LCD. The total operation takes a few seconds.

5. Intended Use:

The device is an electronic clinical thermometer using an infrared sensor to detect the body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

6. Comparison to Predicate Devices:

The OSTI *TempTeller*® Infrared ear thermometer, model CT-30 / CT-30DX, is substantially equivalent to the following infrared ear thermometers.

- *TempTeller*® Infrared Tympanic Thermometer, model TT-201, Oriental System Technology Inc., 510(k) Number: K984497
- Braun ThermoScan® Instant Thermometer, model IRT 3020/3520, Braun AG, 510(k) Number: K 983295

The OSTI *TempTeller*® Infrared Ear Thermometer, model CT-30 / CT-30DX, has the same general design and incorporate similar materials and components as our 510(k) cleared device, model TT-201. The only difference is the IR sensor.

The OSTI *TempTeller*® Infrared Ear Thermometer, model CT-30 / CT-30DX, uses the same sensor technology as the Braun ThermoScan® Instant Thermometer, model IRT 3020 / 3520.

The primary function of the OSTI *TempTeller*® Infrared Ear Thermometer, model CT-30 / CT-30DX, is the same as our 510(k) cleared model TT-201 for the measurement of body temperature and raises no new questions of safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence Are as Follows:

Compliance to applicable voluntary standards includes ASTM E1965-98, and ASTM E1104, as well as IEC601-1-1 and IEC601-1-2 requirements.

Guidance Documents included the FDA "Guidance On the Content of Premarket Notification (510(k)) Submissions for Clinical Electronic Thermometers".

8. Discussion of Clinical Tests Performed:

Controlled human clinical studies were conducted using the OSTI TempTeller® Infrared Ear Thermometer and predicate devices. Clinical data is presented comparing OSTI TempTeller® Infrared Ear Thermometer to the predicate devices. The patient population is well represented (neonatal, pediatrics and adults), and the number of patients have been statistically justified. The clinical test data demonstrated that OSTI TempTeller® Infrared Ear Thermometer, model CT-30 / CT-30DX, measured ear temperature is equivalent to the predicate devices.

9. Conclusions:

The OSTI TempTeller® Infrared Ear Thermometer, model CT-30 / CT-30DX, has the same intended use and similar technological characteristics to our 510(k) cleared device, model TT-201, and Braun ThermoScan® Instant Thermometer, model IRT3020 / 3520. Moreover, bench testing contained in this submission and clinical testing supplied demonstrated that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the OSTI TempTeller® Infrared Ear Thermometer, model CT-30 / CT-30DX, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 9 2001

Oriental System Technology Incorporated
Ms. Susan D. Goldstein-Falk
Official Correspondent
MDI Consultants, Incorporated
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: K010235
Trade/Device Name: TempTeller® Infrared Ear Thermometer, Model CT-30/CT-30DX
Regulation Number: 880.2910
Regulatory Class: II
Product Code: FLL
Dated: April 23, 2001
Received: April 25, 2001

Dear Ms. Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that,

through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devcies
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010235

Device Name: Oriental System Technology Inc. TempTeller® Infrared Ear Thermometer, model CT-30 / CT-30DX

Indications For Use:

This device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the auditory canal in the neonatal, pediatric and adult population used in the home setting.

Patricia Cucente

(Division Sign-Off)
Division of Dental, Infection Control, and General Hospital Devices
510(k) Number K010235

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter Use ✓ (Optional format 1-2-96)